

REMARKS

The Office Action mailed March 31, 2006 has been received and reviewed. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Support for the amendment to claim 1 can be found throughout the as-filed specification and particularly on page 3, lines 12 through 20. No new matter has been entered. Claims 1-26 are pending in the application. Claims 1-19 are currently under examination. All stand rejected. Reconsideration is respectfully requested.

1. Information Disclosure Statement

It was suggested that the Information Disclosure Statement (IDS) filed December 1, 2003 fails to comply with 37 C.F.R. § 1.98(a)(2) as copies of foreign patent documents and non-patent literature publications were not provided. Applicants respectfully submit the previously filed IDS complies with 37 C.F.R. § 1.98(a)(2) by compliance with 37 C.F.R. § 1.98(d). 37 C.F.R. § 1.98(d) provides:

A copy of any patent, publication, pending U.S. application or other information, as specified in paragraph (a) of this section, listed in an information disclosure statement is required to be provided, even if the patent, publication, pending U.S. application or other information was previously submitted to, or cited by, the Office in an earlier application, unless:

- (1) The earlier application is properly identified in the information disclosure statement and is relied on for an earlier effective filing date under 35 U.S.C. 120; and
- (2) The information disclosure statement submitted in the earlier application complies with paragraphs (a) through (c) of this section.

The IDS filed December 1, 2003 included the following statement in compliance with 37 § C.F.R. § 1.98(d)(1):

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/716,612

Filed: November 20, 2000

For: METHODS AND MEANS FOR PREVENTING OR TREATING INFLAMMATION OR PRURITIS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

Applicants submit that the IDS filed in earlier application 09/716,612 complies with paragraphs

(a) through (c) of section 1.98. Therefore, applicants submit that sections 1.98(d)(1) and (2) have been complied with and copies of the foreign patent documents and non-patent literature publications are not required to be provided. Applicants respectfully request the Examiner consider the information referred to in the IDS filed December 1, 2003. If the documents are no longer available at the Office, the Examiner is kindly requested to contact applicants' representative, and copies will be promptly provided as a courtesy.

2. Claims 1-3 and 5-19 and 35 U.S.C. § 102(b)

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by US 4,906,457 ("Ryan"). Specifically, it was thought that Ryan discloses a skin care or topical pharmaceutical composition comprising an inhibitor of proteolytic activity that is derived from potato and a cosmetically or pharmaceutically acceptable vehicle. Applicants respectfully traverse the rejections, at least partially in view of the amendments to the claims.

Applicants respectfully submit that the rejections are moot in light of the amendments to the claims. Applicants submit that Ryan only discloses compositions with a single protease inhibitor from potato. The claims as amended comprise a mixture of more than one protease inhibitor from potato. The effect of the composition is a mixture of the effect of the individual protease inhibitors, and, surprisingly it is this mixture of effects that makes the composition applicable for the specific purposes of the invention (*i.e.*, against the inflammation caused by the proteolytic activity of feces). Applicants' application extensively describes (*see* Table 6 on page 48) that the protease inhibitor mixture from potato juice has both effects on the proteases (chymo)trypsin and elastase. It is submitted that this combination of effects would be responsible for the observed effect on inflammations caused by feces. Applicants submit that Ryan does not describe expressly or inherently a composition comprising at least two protease inhibitors derived from potato.

Furthermore, applicants submit that Ryan does not describe an elastase inhibitor derived from potato. Rather, applicants submit that Ryan discloses generically that elastase inhibitors are commercially available or can be prepared. *Column 2, lines 6-13*. Additionally, Ryan gives no information about the nature of the proteolytic activity of its composition, and the (medical) indications for which Ryan uses its composition is different from the present indication. Ryan

uses its composition for prevention of skin cancer induced by sunlight.

Therefore, for at least the above reasons, Ryan cannot anticipate claim 1. Claims 2, 3, and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

3. Claims 1-3 and 5-19 and 35 U.S.C. § 102(b)

Claims 1-3 and 5-19 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by US 3,950,509 ("Geks"). Specifically, it was thought that Geks discloses a skin care or topical pharmaceutical composition comprising a cosmetically or pharmaceutically acceptable vehicle and a proteolytic activity inhibitor derived from potato that includes kallikrein-trypsin inhibitor derived from potatoes. Applicants respectfully traverse the rejections, at least partially in view of the amendments to the claims.

Applicants respectfully submit that the rejections are moot in light of the amendments to the claims. The claims as amended comprise a mixture of more than one protease inhibitor from potato. The effect of the composition is a mixture of the effect of the individual protease inhibitors, and, surprisingly it is this mixture of effects that makes the composition applicable for the specific purposes of the invention (*i.e.*, against the inflammation caused by the proteolytic activity of feces). Applicants' application extensively describes (*see* Table 6 on page 48) that the protease inhibitor mixture from potato juice has both effects on the proteases (chymo)trypsin and elastase. It is submitted that this combination of effects would be responsible for the observed effect on inflammations caused by feces. Geks appears to disclose that more than one protease inhibitor from potato can be used. Applicants submit that Geks does not describe expressly or inherently a composition comprising at least a combination of a trypsin inhibitor and an elastase inhibitor.

Additionally, Geks gives no information about the nature of the proteolytic activity of its composition, and the (medical) indications for which Geks uses its composition is different from the present indication. Geks uses its composition for prevention of transpiration odour.

Therefore, for at least the above reasons, Geks cannot anticipate claim 1. Claims 2, 3, and 5-19 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

4. Claims 1, 2, 4-6, 12, and 13 and 35 U.S.C. § 102(b)

Claims 1, 2, 4-6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Rodis *et al.*, (“Naturally occurring protein crystals in the potato”. Plant Physiol. 1984, 74:907-911) (“Rodis”). Specifically, it was thought that Rodis discloses a composition comprising a proteolytic activity inhibitor derived from potato and a cosmetically or pharmaceutically acceptable vehicle such as sodium acetate buffer. Applicants respectfully traverse the rejections, at least partially in view of the amendments to the claims.

Applicants respectfully submit that the rejections are moot in light of the amendments to the claims. Applicants submit that Rodis only discloses compositions with a single protease inhibitor from potato. The claims as amended comprise a mixture of more than one protease inhibitor from potato. The effect of the composition is a mixture of the effect of the individual protease inhibitors, and, surprisingly it is this mixture of effects that makes the composition applicable for the specific purposes of the invention (*i.e.*, against the inflammation caused by the proteolytic activity of feces). Applicants’ application extensively describes (*see* Table 6 on page 48) that the protease inhibitor mixture from potato juice has both effects on the proteases (chymo)trypsin and elastase. It is submitted that this combination of effects would be responsible for the observed effect on inflammations caused by feces. Applicants submit that Rodis does not describe expressly or inherently a composition comprising at least two protease inhibitors derived from potato. Furthermore, applicants submit that Rodis does not describe an elastase inhibitor derived from potato.

Therefore, for at least the above reasons, Rodis cannot anticipate claim 1. Claims 2, 4-6, 12, and 13 are not anticipated as, *inter alia*, depending from an unanticipated base claim. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

5. Claims 1-19 and 35 U.S.C. § 103(a)

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Ryan and Geks taken with Rodis. Specifically, it was thought that Ryan and Geks are silent about the pH of compositions with potato inhibitors. It was suggested that Rodis teaches that potato protease inhibitors are readily dissolved at pH 4-5 unlike neutral or alkaline pH. It was

asserted that one of skill in the art would have been motivated to use acidic pH for making aqueous compositions with potato-derived protease inhibitors for the expected benefits in fully dissolving active ingredients. Applicants respectfully traverse the rejections, at least partially in view of the amendments to the claims.

Applicants respectfully submit that the rejections are moot in light of the amendments to the claims. Neither Ryan, Geks, nor Rodis teach or suggest "a skin care or topical pharmaceutical composition comprising at least a combination of a trypsin inhibitor and an elastase inhibitor and a cosmetically or pharmaceutically acceptable vehicle, and wherein the inhibitors are derived from potato." As said above, Ryan and Rodis do not mention combinations of protease inhibitors from potato, nor would it be obvious to use such combinations from either of said documents. Geks mentions combinations, but none of the references specify the activity profiles of such combinations. Neither do the references make obvious that the combination of a (chymo)trypsin inhibitor and an elastase inhibitor would have a potent cosmetic or pharmaceutical effect. Therefore, claim 1 is non-obvious and claims 2-19 are non-obvious for depending therefrom. In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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